

EXPRESS MAIL NO. EV336597813US

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants : Martin A. Cheever and Mary L. Disis
Filed : August 21, 2003
For : IMMUNE REACTIVITY TO HER-2/*neu* PROTEIN FOR
DIAGNOSIS AND TREATMENT OF MALIGNANCIES IN
WHICH THE HER-2/*neu* ONCOGENE IS ASSOCIATED
Docket No. : 920010.448C10
Date : August 21, 2003

Mail Stop Patent Application
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Commissioner for Patents:

In accordance with 37 C.F.R. §§ 1.56 and 1.97 through 1.98, Applicants wish to make known to the Patent and Trademark Office the references set forth on the attached Forms PTO-1449. This application is a continuation and relies, under 35 U.S.C. § 120, on the earlier filing date of prior application USAN 09/354,533, filed July 15, 1999, now allowed; which is a continuation of USAN 08/466,680, filed June 6, 1995, which issued as United States Letters Patent No. 6,075,122; which is a continuation of USAN 08/414,417, filed March 31, 1995, now issued as United States Letters Patent No. 5,801,005; which is a continuation-in-part of USAN 08/106,112, filed August 12, 1993, now abandoned; which is a continuation-in-part of USAN 08/033,644, filed March 17, 1993, now abandoned. The references listed on the attached Forms PTO-1449 were submitted to and/or cited by the Patent and Trademark Office in these prior applications and, therefore, are not required to be provided in this application. If the Examiner wishes, copies will be provided upon request.

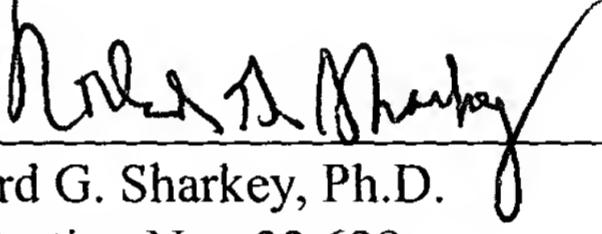
As to any reference previously supplied, Applicants do not admit that it is "prior art" under 35 U.S.C. §§ 102 or 103, and specifically reserve the right to traverse or antedate any

such reference, as by a showing under 37 C.F.R. § 1.131 or other method. Although the aforesaid references are made known to the Patent and Trademark Office in compliance with Applicants' duty to disclose all information they are aware of which is believed relevant to the examination of the above-identified application, Applicants believe that their invention is patentable.

Please acknowledge receipt of this Information Disclosure Statement and kindly make the cited references of record in the above-identified application.

Applicants believe this Information Disclosure Statement has been timely filed, however, the Commissioner is authorized to charge any fee due by way of this Information Disclosure Statement to our Deposit Account No. 19-1090.

Respectfully submitted,
Seed Intellectual Property Law Group PLLC



Richard G. Sharkey, Ph.D.
Registration No. 32,629

RGS:ljt

Enclosures:

Forms PTO-1449 (7 Sheets)

701 Fifth Avenue, Suite 6300
Seattle, Washington 98104-7092
Phone: (206) 622-4900
Fax: (206) 682-6031

\410783

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		APPLICANTS Martin A. Cheever and Mary L. Disis			
		FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned		

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	3,766,162	10/1973	Spector	260	112.R	
	AB	3,791,932	02/1974	Schuurs et al.	195	103.5R	
	AC	3,817,837	06/1974	Rubenstein et al.	195	103.5R	
	AD	3,850,752	11/1974	Schuurs et al.	195	103.5R	
	AE	3,901,654	08/1975	Gross	23	230.B	
	AF	3,935,074	01/1976	Rubenstein et al.	195	103.5R	
	AG	3,984,533	10/1976	Uzgiris	424	12	
	AH	3,996,345	12/1976	Ullman et al.	424	12	
	AI	4,034,074	07/1977	Miles	424	1	
	AJ	4,098,876	07/1978	Piasio et al.	424	1	
	AK	4,233,402	11/1980	Maggio et al.	435	7	

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL	WO 90/14357	11/1990	PCT		
	AM	WO 91/02062	02/1991	PCT		
	AN					
	AO					
	AP					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

AQ		Alper et al., "The Presence of c-erbB-2 Gene Product-related Protein in Culture Medium Conditioned by Breast Cancer Cell Line SK-BR-3," <i>Cell Growth & Differentiation</i> 1:591-599, 1990.
AR		Bargmann et al., "The neu oncogene encodes an epidermal growth factor receptor-related protein," <i>Nature</i> 319:226-230, 1986.
AS		Baselga et al., "Phase II Study of Weekly Intravenous Recombinant Humanized Anti-p185(^HER2) Monoclonal Antibody in Patients With HER2/neu-Overexpressing Metastatic Breast Cancer," <i>Journal of Clinical Oncology</i> 14(3): 737-744, 1996.

EXAMINER	DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				APPLICANTS Martin A. Cheever and Mary L. Disis	
				FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
	AA	4,452,901	06/1984	Gordon et al.	436	506	
	AB	5,320,947	06/1994	Cheever et al.	435	29	
	AC	5,401,638	03/1995	Carney et al.	435	7.23	
	AD	5,958,784	09/28/99	Benner	436	86	
	AE	5,985,553	11/16/99	King et al.	435	6	
	AF						
	AG						
	AH						
	AI						
	AJ						
	AK						

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION	
					YES	NO
	AL					
	AM					
	AN					
	AO					
	AP					

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

AQ		Ben-Mahrez et al., "Circulating Antibodies Against C-myc Oncogene Product In Sera Of Colorectal Cancer Patients," <i>Int. J. Cancer</i> 46: 35-38, 1990.
AR		Bishop and Orosz, "Limiting Dilution Analysis For Alloreactive, TCGF-Secretory T Cells. Two Related LDA Methods That Discriminate Between Unstimulated Precursor T Cells and In Vivo-Alloactivated T Cells," <i>Transplantation</i> 47(4): 671-677, 1989.
AS		Bodmer, W., "T-Cell Immune Responses to Cancer--A New Look," <i>Human Immunology</i> 30:259-261, 1991.

EXAMINER	DATE CONSIDERED

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		APPLICANTS Martin A. Cheever and Mary L. Disis			
		FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned		

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	

OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
AA		Bowen-Pope et al., "Production of platelet-derived growth factor-like molecules and reduced expression of platelet-derived growth factor receptors accompany transformation by a wide spectrum of agents," <i>Proc. Natl. Acad. Sci. USA</i> 81: 2396-2400, 1984.					
AB		Brooks et al., "Human lymphocyte markers defined by antibodies derived from somatic cell hybrids," <i>Clin. Exp. Immunol.</i> 39: 477-485, 1980.					
AC		Brown et al., "Protein Antigens of Normal and Malignant Human Cells Identified by Immunoprecipitation with Monoclonal Antibodies," <i>Journal of Biological Chemistry</i> 255(11): 4980-4983, 1980.					
AD		Burnette et al., "Western Blotting: Electrophoretic Transfer of Proteins from Sodium Dodecyl Sulfate-Polyacrylamide Gels to Unmodified Nitrocellulose and Radiographic Detection with Antibody and Radioiodinated Protein A," <i>Analytical Biochemistry</i> 112: 195-203, 1981.					
AE		Coussens et al., "Tyrosine Kinase Receptor with Extensive Homology to EGF Receptor Shares Chromosomal Location with neu Oncogene," <i>Science</i> 230: 1132-1139, 1985.					
AF		Dhut et al, "BCR-ABL and BCR Proteins: Biochemical Characterization and Localization," <i>Leukemia</i> 4(11): 745-750, 1990.					
AG		Disis et al., "Existent T-Cell and Antibody Immunity to HER-2/neu Protein in Patients With Breast Cancer," <i>Cancer Res.</i> 54: 16-20, 1994.					
AH		Falk et al., "Allele-specific motifs revealed by sequencing of self-peptides eluted from MHC molecules," <i>Nature</i> 351: 290-296, 1991.					
AI		Feller and de la Cruz, "Identifying antigenic T-cell sites," <i>Nature</i> 349: 720-721, 1991.					
AJ		Fisk et al., "Oligopeptide Induction of a Cytotoxic T Lymphocyte Response to HER-2/Neu Proto-oncogene in Vitro," <i>Cellular Immunology</i> 157:415-427, 1994.					
AK		Flanagan and Leder, "neu protooncogene fused to an immunoglobulin heavy chain gene requires immunoglobulin light chain for cell surface expression and oncogenic transformation," <i>Proc. Natl. Acad. Sci. USA</i> 85: 8057-8061, 1998.					
EXAMINER				DATE CONSIDERED			

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				APPLICANTS Martin A. Cheever and Mary L. Disis	
				FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned

U.S. PATENT DOCUMENTS

*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
-------------------	--	-----------------	------	------	-------	----------	----------------------------

FOREIGN PATENT DOCUMENTS

		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION
					YES NO

OTHER PRIOR ART *(Including Author, Title, Date, Pertinent Pages, Etc.)*

AA		Igelhart et al., "Increased erbB-2 Gene Copies and Expression in Multiple Stages of Breast Cancer," <i>Cancer Research</i> 50: 6701-6707, 1990.
AB		Ioannides et al., "Antigens Recognized by T cells in Ovarian Cancer," in Abstracts of the Fourth International Conference of Anticancer Research, 21-25 Oct. 1992, Rethymnon, Crete, Greece, p. 1870.
AC		Ioannides et al., "CTL Clones Isolated from Ovarian Tumor Infiltrating Lymphocytes can Recognize Peptides with Sequences Corresponding to the HER2/neu Gene Product," <i>FASEB Journal</i> 6: A1404, Abstract No. 2711, 1992.
AD		Ioannides et al., "Cytotoxic T Cells Isolated From Ovarian Malignant Ascites Recognize a Peptide Derived From the HER-2/neu Proto-oncogene," <i>Cell. Immunol.</i> 151: 225-234, 1993.
AE		Ioannides et al., "Cytotoxic T-Cell Clones Isolated from Ovarian Tumour Infiltrating Lymphocytes Recognize Common Determinants on Non-Ovarian Tumour Clones," <i>Scand. J. Immunol.</i> 37: 413-424, 1993.
AF		Ioannides et al., "T-Cell Recognition of Oncogene Products: A New Strategy for Immunotherapy," <i>Molecular Carcinogenesis</i> 6: 77-82, 1992.
AG		Ioannides, Abstracts Fourth International Conference of Anticancer Research 21-25 Oct. 1992 p. 1870.
AH		Ioannides, "Antigens and vaccines of female genital cancers (Meeting abstract)," Cancerlit Database Abstract No. ICDB/93690682, 1992.
AI		Ioannides, et al., "Cytotoxic T Cells Isolated From Ovarian Malignant Ascites Recognize a Peptide Derived From the HER-2/neu Proto-oncogene," <i>Cell. Immunol.</i> 151:225-234, 1993.
AJ		Ioannides, Society for Biological Therapy 1992 Annual Meeting, p. 27 Oct. 29-Nov. 1, 1992.
AK		Kallioniemi et al., "ERBB2 amplification in breast cancer analyzed by fluorescence in situ hybridization," <i>Proc. Natl. Acad. Sci.</i> 89: 5321-5325, 1992.

EXAMINER	DATE CONSIDERED
----------	-----------------

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>		APPLICANTS Martin A. Cheever and Mary L. Disis			
		FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned		

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	

OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
	AA	Kerns et al., "c-erbB-2 Expression In Breast Cancer Detected by Immunoblotting and Immunohistochemistry," <i>Journal of Histochemistry and Cytochemistry</i> 38(12): 1823-1830, 1990.					
	AB	Laemmli, U., "Cleavage of Structural Proteins during the Assembly of the Head of Bacteriophage T4," <i>Nature</i> 227: 680-685, 1970.					
	AC	Leitzel et al., "Elevated Soluble c-erbB2 Antigen Levels in the Serum and Effusions of a Proportion of Breast Cancer Patients," <i>Journal of Clinical Oncology</i> 10(9): 1436-1443, 1992.					
	AD	Lichtenstein et al., "Effects of .beta.-2 Microglobulin Anti-sense oligonucleotides on Sensitivity of HER2/neu Oncogene-Expressing and Nonexpressing Target Cells to Lymphocyte-Mediated Lysis," <i>Cellular Immunology</i> 141: 219-232, 1992.					
	AE	Lippman, M., "Potential Contributions of Breast Cancer Biology to Management of Breast Cancer," <i>Advances in Oncology</i> 8(3): 26-28, 1992.					
	AF	Lippman, M., "Potential Contributions of Breast Cancer Biology to Management of Breast Cancer", <i>Advances in Oncology</i> 8(3): 26-28, 1992.					
	AG	Maguire and Greene, "The neu (c-erbB-2) Oncogene," <i>Seminars in Oncology</i> 16(2): 148-155, 1989.					
	AH	Margalit et al., "Prediction Of Immunodominant Helper T Cell Antigenic Sites From The Primary Sequence," <i>Journal of Immunology</i> 138(7): 2213-2229, 1987.					
	AI	McGlynn et al., "Large-scale purification and characterisation of a recombinant epidermal growth-factor receptor protein-tyrosine kinase. Modulation of activity by multiple factors," <i>Eur. J. Biochem.</i> 207: 265-275, 1992.					
	AJ	McKenzie et al., "Induction of Antitumor Immunity by Immunization with a Vaccinia Virus Vector Expressing and Oncogene-encoded Product," in <i>Vaccines 88</i> , Cold Spring Harbor Laboratory, 1988, pp. 19-23.					
	AK	Mietzner et al., "Purification and Characterization of the Major Iron-Regulated Protein Expressed By Pathogenic Neisseriae," <i>Journal of Experimental Medicine</i> 165: 1041-1057, 1987.					
EXAMINER				DATE CONSIDERED			

* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).

FORM PTO-1449 (REV.7-80)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				APPLICANTS Martin A. Cheever and Mary L. Disis	
				FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned

U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE

FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	

OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
AA		Mori et al., "In Vitro and in vivo Release of Soluble erbB-2 Protein from Human Carcinoma Cells," <i>Japanese Journal of Cancer Research</i> 81: 489-494, 1990.					
AB		Paik et al., "Pathologic Findings From the National Surgical Adjuvant Breast and Bowel Project: Prognostic Significance of erbB-2 Protein Overexpression in Primary Breast Cancer," <i>Journal of Clinical Oncology</i> 8(1): 103-112, 1990.					
AC		Parker et al., "Sequence Motifs Important For Peptide Binding To The Human MHC Class I Molecule, HLA-A2," <i>Journal of Immunology</i> 149(11): 3580-3587, 1992.					
AD		Press et al., "Expression of the HER-2/neu proto-oncogene in normal human adult and fetal tissues," <i>Oncogene</i> 5: 953-962, 1990.					
AE		Raines and Ross, "Platelet-derived Growth Factor. I. High Yields Purification and Evidence for Multiple Forms," <i>Journal of Biological Chemistry</i> 257(9): 5154-5159, 1982.					
AF		Riberdy and Cresswell, "The Antigen-Processing Mutant T2 Suggests a Role for MHC-Linked Genes in Class II Antigen Presentation," <i>Journal of Immunology</i> 148(8):2586-2590, 1992.					
AG		Rothbard and Taylor, "A sequence pattern common to T cell epitopes," <i>EMBO Journal</i> 7(1): 93-100, 1988.					
AH		Semba et al., "A v-erbB-related protooncogene, c-erbB-2, is distinct from the c-erbB-1/epidermal growth factor-receptor gene and is amplified in a human salivary gland adenocarcinoma," <i>Proc. Natl. Acad. Sci. USA</i> 82: 6497-6501, 1985.					
AI		Spies et al., "A gene in the human major histocompatibility complex class II region controlling the class I antigen presentation pathway," <i>Nature</i> 348: 744-747, 1990.					
AJ		Stern et al., "Oncogene Activation of p185(^neu) Stimulates Tyrosine Phosphorylation In Vivo," <i>Molecular and Cellular Biology</i> 8(9): 3969-3973, 1988.					
AK		Trowsdale et al., "Sequence encoded in the class II region of the MHC related to the 'ABC' superfamily of transporters," <i>Nature</i> 348: 741-744, 1990.					
EXAMINER				DATE CONSIDERED			
<i>* EXAMINER:</i> Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).							

FORM PTO-1449 (REV.7-80) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE				ATTY. DOCKET NO. 920010.448C10	APPLICATION NO. Not Assigned		
INFORMATION DISCLOSURE STATEMENT <i>(Use several sheets if necessary)</i>				APPLICANTS Martin A. Cheever and Mary L. Disis			
				FILING DATE August 21, 2003	GROUP ART UNIT Not Assigned		
U.S. PATENT DOCUMENTS							
*EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	FILING DATE IF APPROPRIATE
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY		TRANSLATION	
						YES	NO
OTHER PRIOR ART <i>(Including Author, Title, Date, Pertinent Pages, Etc.)</i>							
AA		Weiner et al., "A point mutation in the neu oncogene mimics ligand induction of receptor aggregation," <i>Nature</i> 339: 230-231, 1989.					
AB		Wide, L., "Solid Phase Antigen-Antibody Systems," in <i>Radioimmunoassay Methods</i> , Kirkham and Hunter (eds.), 1973, pp. 405-412.					
AC		Wisdom, G.B., "Enzyme-Immunoassay," <i>Clin. Chem.</i> 22(8): 1243-1255, 1976.					
AD		Yamamoto et al., "Similarity of protein encoded by the c-erb-B-2 gene to epidermal growth factor receptor," <i>Nature</i> 319: 230-234, 1986.					
AE		Zabrecky et al., "The Extracellular Domain of p185/neu Is Released from the Surface of Human Breast Carcinoma Cells, SK-BR-3," <i>Journal of Biological Chemistry</i> 266(3): 1716-1720, 1991.					
AF							
AG							
AH							
AI							
AJ							
AK							
EXAMINER				DATE CONSIDERED			
* EXAMINER: Initial if reference considered, whether or not criteria is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant(s).							